

## Summary

Applicant respectfully requests an Examiner interview, if the above amendments  
5 and the supporting Affidavits do not place this application in a condition of allowance.  
Applicant authorizes the Commissioner for Patents to charge Deposit Account number  
190254 for any late fees or charges necessary to avoid abandonment. I can be  
reached direct at (508) 261-8476 or [Edward.jarmolowicz@tycohealthcare.com](mailto:Edward.jarmolowicz@tycohealthcare.com).

10 Respectfully yours,



Edward S. Jarmolowicz, Reg. No. 47,238  
Attorney for the Applicant  
15 Tyco Healthcare Group LP d/b/a/ Covidien  
15 Hampshire Street  
Mansfield, MA 02048

January 23, 2008

Commissioner for Patents  
Attention of Examiner Towa  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313

Dear Examiner:

I am an engineer currently employed by the assignee of the Applicant. I am familiar with the current design that is found in the Lantz application. I have read the Sato reference and understand its operation.

I consider myself having the necessary skill in the art to understand the inventions. I have worked in the field of medical device technology for ten years. I have worked on thermometers of the type described in Sato, for example, my joint invention at U.S. Patent Number 7,316,507. I respectfully suggest that modifying Sato to operate as the claimed invention, the Sato reference would be inoperable.

The Sato collar 13 is a stationary body including the cover mounting portion 13c. The button 15 is integral or formed as part of the probe shaft. The collar houses the probe shaft assembly and allows it to slide in a linear direction to eject the probe shaft cover. The shaft and spring are trapped in the collar by cap 25 and button 15. The button and shaft slide as one piece during the mounting and ejection of the probe cover. The spring works to keep the tip of the shaft seated in the probe cover tip area for good thermal conductivity. The retaining means 19 works like a friction lock between probe cover 12 and collar 13 when probe cover 12 is slide on probe shaft 14. When probe cover 12 is engaged on to probe shaft 14, the shaft and button will move with probe cover 12 until probe cover 12 bottoms out in a friction fit with retainer means 19. In other words the shaft and button are dependent on one another. When the probe shaft moves the button moves the same amount of distance. The spring is used to

rebound the shaft assembly and insure the tip is always in contact with the probe cover tip. The probe shaft assembly is used to eject the probe cover.

In the Lantz patent application, the probe shaft and button are independent from one another. Lantz does use a spring to rebound the probe shaft to ensure the tip stays in contact with the probe cover tip, but that is where the similarities with Sato end. The single spring in the Lantz patent application is used in two manners. It is used to rebound the button and the shaft independent of one another. In other words, if you push the button to eject the probe cover, that is all that happens. The button does not move the shaft forward. If you put a probe cover on the shaft assembly the button does not move. The probe shaft moves inward a small amount under the spring force when the probe cover is attached. The button has fingers built into it that push on the end of the probe cover to eject it. The fingers are under the influence of the spring, not the probe shaft. Although the probe shaft assembly moves forward as well, it is not caused by the action of the button. It is caused by the spring force acting on it. The probe cover ejection motion is caused by the button fingers applying a force to the probe cover. The small amount of movement of the probe shaft, on the order of no more than a 100<sup>th</sup> of an inch is to make sure the tip completely engages the probe cover, for proper heat transfer between the patient and the tip.

The retention of the probe cover is totally different, in the present invention. The Lantz patent application has a retention under-cut on the probe handle and small protrusions in the probe cover to lock the probe cover on the probe shaft assembly. Support is found at claim 2 in Lantz. When the probe cover is slid onto the probe shaft assembly the three retaining features are deformed enough to pass by the retainer diameter. When the probe cover retaining features reach the probe shaft under cut ring they expand outward locking the probe cover in place. During ejection these retaining features are deformed again enough to slide over the probe shaft housing and eject the probe cover.

Based on my understanding of Sato, a mere reversal of the parts will result in an inoperable device because the Sato button must be separated from

the Sato shaft. Thus, the button would not move the Sato shaft and the used probe cover would not be ejected from the shaft.

The user by pushing on the Sato button and shaft combination, the integral combination overcomes the retention features of Sato and its spring, which is used to bias the cover against the tip to ensure proper contact of the tip with the probe cover. Proper contact is to ensure the best heat transfer through the plastic to the metal tip which is part of the sensing electronics to read the patient temperature. The Sato device is constructed as a one-piece device with the spring in the housing, and by contrast the Lantz button, probe shaft, spring and at least one eject finger operate independently of each other to eject the used probe cover.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ricky A. Sisk". The signature is fluid and cursive, with the first name "Ricky" being more prominent.

Ricky Sisk

Engineer

May 02, 2007

Commissioner for Patents  
Attention of Examiner Towa  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313

Dear Examiner:

I am an inventor of U.S. Patent Application Serial No. 10/538,543.

My invention answers a long understood need, in the medical field, to reduce the spread of germs from patient to patient when using a medical device designed for repeated use. Prior art thermometers expose a portion of the probe shaft because prior art probe covers, that I am aware of, do not completely cover the probe shaft. The exposure of the shaft in close proximity to a body part, such as when placed into a patient's ear or mouth, allows for human hair, skin and bodily fluids to collect at the exposed shaft over repeated uses by a nurse.

To prevent the transfer of germs from the exposed portions at the thermometer shaft to the next patient, I designed the probe shaft and ejection mechanism, so the probe cover would cover the shaft and ejection fingers. This provided a sanitary barrier between the shaft/ejection fingers and human body parts to reduce the spread of germs. After use, the probe cover is ejected from the probe tip and disposed in a medical waste container. The next design issue was to eject the installed cover from the retaining means for the cover to the shaft, without exposing the ejection mechanism to the body parts of a patient or to the used (dirty) probe cover. I designed the cover to overlay the ejection mechanism. My ejection mechanism moves a finger under the force imparted by depressing a button, the finger moves beneath the cover, distally along the surface of the probe shaft, and the finger strikes a pre-positioned protrusion at the inner surface of the cover, which releases the cover from the retaining means at the probe shaft.

I have reviewed U.S. Patent No. 3,738,173 to Sato. Sato ejects its probe cover using the probe shaft to dislodge the cover from a retaining means formed in a collar. The collar is positioned around the probe shaft. The retaining means 19 holds the cover onto the collar and over the probe shaft when the cover is installed for taking a temperature measurement. The collar is concentric around the probe shaft of Sato. The Sato shaft moves up through the opening in the collar during cover insertion, and the shaft is pushed down through the collar opening during over ejection. To remove or eject the used cover from the probe, the user depresses a button forcing the probe shaft distally (away from the user). The force imparted via the button releases the cover from the retaining means at the collar, not at the probe shaft of Sato and the previously compressed spring is released, imparting additional energy to propel the cover beyond the tip of the probe shaft, so the user need not physically remove the dirty cover from the probe shaft.

My invention has a button for dislodging the cover from a retaining means. Likewise, a

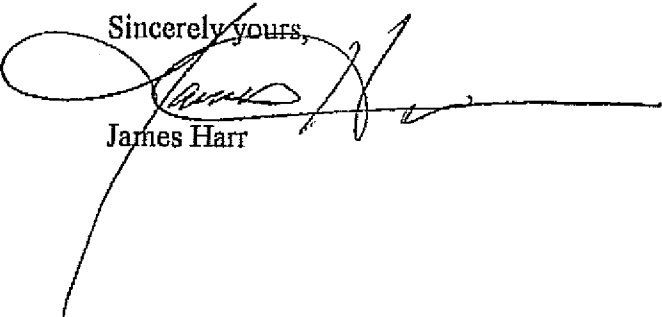
spring is released to help propel the installed cover beyond the distal end of the probe shaft or tip, so the user does not need to handle the dirty cover.

The difference between Sato and my invention is that in Sato, its button moves the probe shaft distally to eject the probe cover. In my invention, the button moves a finger distally along the outer surface of the probe tip beneath the cover. The moving finger dislodges the cover from the retaining means at the probe shaft.

My invention is structurally different from Sato. My finger moves distally along the shaft while in Sato, the proposed finger at collar position 13c remains fixed under the energy delivered by depressing the button. The intended and proper use of the Sato probe is shown at Figure 3. In my opinion, depressing end cap 25 to eject the probe cover of Sato is not possible, as described below. Applying a force by pressing on end cap 25, of Sato, moves the cover, collar and spring as a single assembly along the concentric probe shaft. The cover and collar move as a single assembly because the force imparted at the end cap is not transmitted to the probe shaft, to move the probe shaft distally to eject the probe cover off the retaining means 19 attaching the cover to the collar 13 in Sato. As described above, depressing the button of Sato imparts the pushing force of the human finger to the Sato shaft to overcome the retaining means of Sato, which holds the cover onto the collar. There is no structure to transmit the energy, applied at the end cap 25, to the probe shaft as the Sato shaft freely moves within the concentric opening at the collar. Since the collar is attached to the probe cover at the retaining means 19 the cover is not dislodged by applying a force at end cap 25.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,



James Harr

January 23, 2008

Commissioner for Patents  
Attention of Examiner Towa  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313

Dear Examiner:

I am a Registered Nurse and public health currently employed by the assignee of the Applicant. I have 9 years of experience in the areas of healthcare using these types of devices.

I have worked in the field of medical device technology for 4 years.

In Lantz (US Patent Application 2006/0120432A1), Figure 8, our probe cover 32 is flush with the distal end 24 of the thermometer 20. The cover 32 covers the heat sensing 22 probe tip shown in figure 10. As stated in paragraph 10, the cover is hygienic to provide a sanitary barrier. This barrier as shown in figure 8 covers the probe tip 22 during use. This prevents build up of patient discharge which may harbor infectious material/debris that can serve as a source for infection for the patient as well as a source for contamination of other patients. Fomites, or microbes on inanimate objects can be transferred from one patient to another, this is known as cross contamination .

At Sato (US Patent 3,738,173), figure 10 shows a probe cover 12. The probe cover is shown attached to the probe in Figure 4 and partially covers the collar 13. The collar 13 is exposed as shown at A-A'. This exposed area is shown between A-A' and is an area in which germs are deposited from a patient and allow for cross contamination.

At Makita (US Patent 5,340,215), figure 3 shows a probe cover 9. The probe cover is shown attached to a probe 3 and partially covers a probe tip 4. The tip is exposed as shown at B-B'. This exposed area is between B-B' and is an area in which germs are deposited from a patient and allow for cross contamination.

As noted above, the exposed area provides microbes and potential pathogenic microbes the opportunity to populate the device. In doing so, this can serve as a source of infection for the patients. Because one thermometer is used to serve many patients and only the probe covers are exchanged between patients, debris left behind harboring microbes can be carried and transmitted to other patients. This can be especially damaging to healthcare protocols that intend to contain the spread of infection.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,

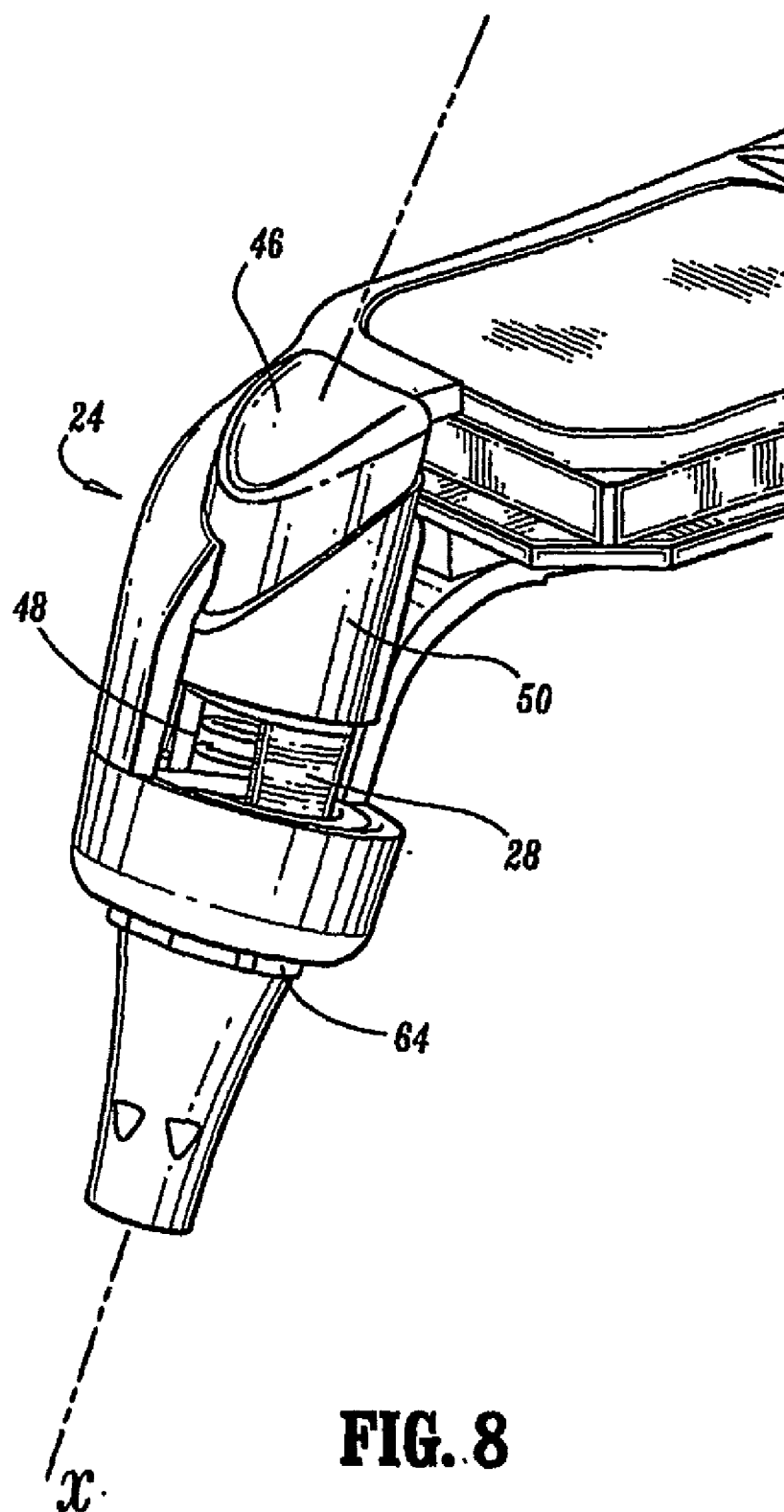
A handwritten signature in black ink, appearing to read 'Loredana Jinga SSN, MPA'.

Loredana Jinga, RN

Attachments

Affidavit Exhibits 1, 2, and 3.





**PATENTED JUN 12 1973**

3,738,173

**SHEET 2 OF 3**

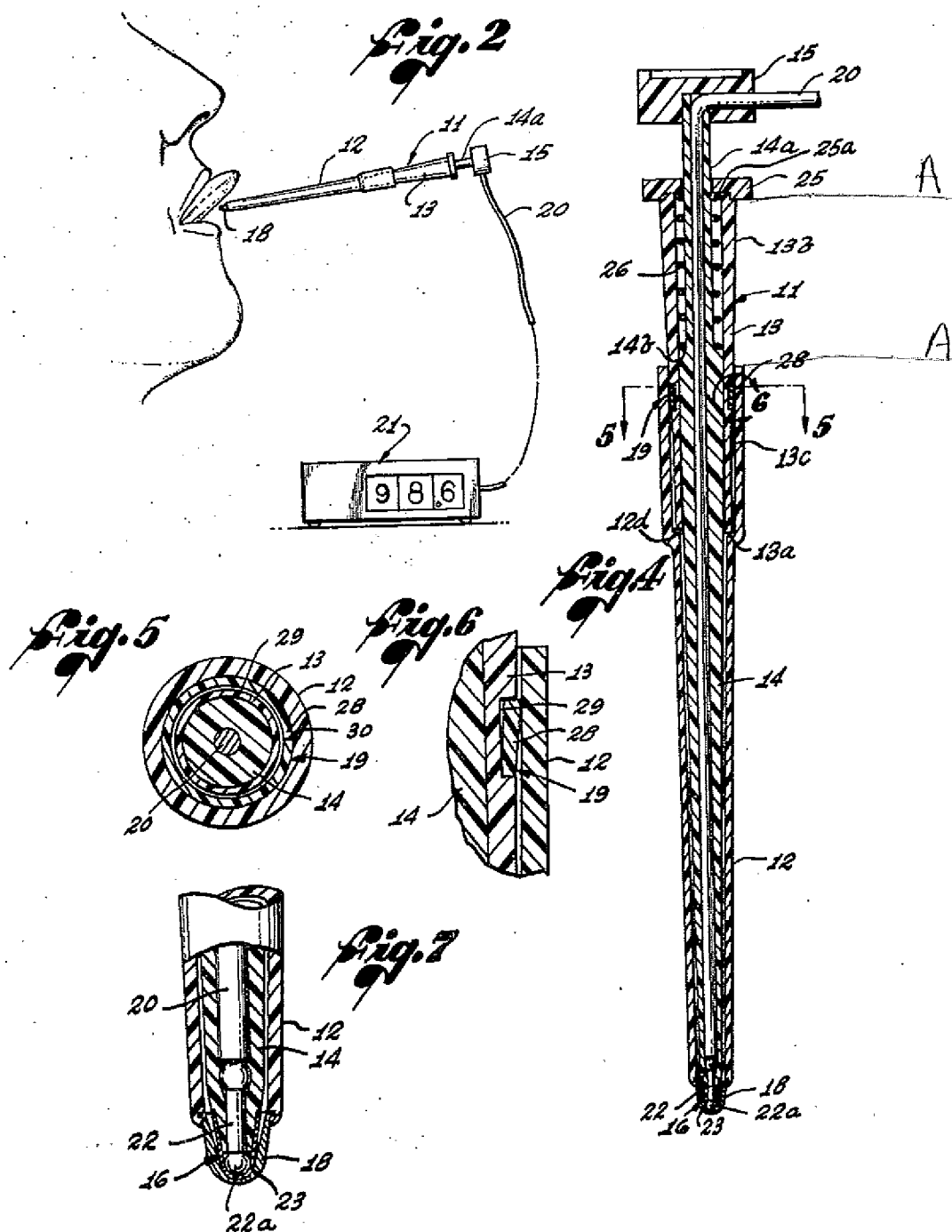


Fig. 3

